DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 9141d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

June 15, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Robert S. Chaloner
Chief Executive Officer
FHSNJ - St. Mary Hospital
308 Willow Avenue
Hoboken, New Jersey 07030

FILE NO.: 01-NWJ-27
Inspection ID NO.: 1398160006

Dear Mr. Chaloner:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on May 25, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Your facility processed mammograms using Processor #1 ([redacted] when it was out of limits on at least [redacted] days within the past year.**

- **Phantom Quality Control (QC) records for Unit #1 ([redacted] documenting performance of phantom image testing were missing for 12 weeks. The missing QC records were for the following weeks: 6/07/00, 6/28/00, 7/06/00, 7/28/00, 8/02/00, 8/07/00, 8/14/00, 8/21/00, 9/20/00, 10/04/00, 5/01/02 and 5/09/01.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level One findings because they identify a failure to comply with a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspending or revoking your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- Corrective actions were not documented when Processor #1 [redacted] exceeded preset parameters.

- Processor QC records for Processor #1 [redacted], which document the performance of quality control testing, were missing for the following dates: 6/09/00, 7/13/00, 7/14/00, 8/12/00, 8/19/00, 8/24/00 and 9/30/00.

- The background density of the phantom image was less than the required 1.20 optical density on five occasions (11/22/00, 12/27/00, 1/03/01, 1/11/01 and 5/16/01).

  During the 5/25/01 inspection, the MQSA inspector conducted phantom image testing and the background density of the phantom image was less than the required 1.20 optical density.

- Your facility failed phantom image testing for Unit #1 [redacted]; however you continued to perform patient exams on 11/22/00, 12/27/00, 1/03/01, 1/11/01 and 5/16/01 without documenting any corrective actions.

- Your facility failed to produce documentation verifying that [redacted] and [redacted] meet the requirement of having interpreted or multi-read 960 mammograms in the 24 months proceeding the date of your inspection.

- Your facility failed to perform an annual medical audit and outcome analysis for your facility as a whole, and for each individual radiologist.

You must act on this matter immediately. Please explain or provide to this office in writing within 15 working days from the date that you receive this letter:

- the specific steps you have taken to correct the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records.

Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during the inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 862-3591 x159.

Sincerely,

Douglas I. Ellsworth

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

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